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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,049	10/02/2001	Chih-Ming Chen	300.1033US	8670
23280	7590	10/15/2003	EXAMINER	
DAVIDSON, DAVIDSON & KAPPEL, LLC			OH, SIMON J	
485 SEVENTH AVENUE, 14TH FLOOR			ART UNIT	
NEW YORK, NY 10018			PAPER NUMBER	

1615

DATE MAILED: 10/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/970,049

Applicant(s)

CHEN, CHIH-MING

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Papers Received*

Receipt is acknowledged of the applicant's petition for extension of time, amendment, and response, all received on 11 August 2003.

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 3 under 35 U.S.C. 102(b) as being anticipated by Assargren *et al.* is hereby withdrawn.

### *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Eek in view of Depui *et al.* is maintained.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Källgren (U.S. Patent No. 6,253,920 B1) in view of Depui *et al.*

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The Källgren patent teaches blister pack comprising at least a first and second row of blisters, perforated in such a way that individual blisters may be individually separated from the pack (See Abstract; Column 2, Lines 38-52; and Figures). The disclosed blister pack may be used for drugs such as omeprazole. Additionally, the blister pack is useful for packaging drugs that should be administered in combination (See Column 3, Lines 4-41).

The Källgren patent does not explicitly teach the use of the disclosed pack with a combination of a proton pump inhibitor and a non-steroidal anti-inflammatory drug.

The Depui *et al.* patent teaches a drug combination comprising a proton pump inhibitor and a non-steroidal anti-inflammatory drug (See Abstract). Omeprazole and diclofenac are given as suitable drugs for use in this combination (See Column 6, first structure; Column 8, Lines 9-13; and Example 6). The use of these drugs in separate dosage forms in a combination therapy in the prior art is acknowledged in the disclosure (See Column 2, Lines 32-40).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of Källgren and Depui *et al.* into the objects of the instantly claimed invention. It is the position of the examiner that one of ordinary skill would be motivated to combine the disclosures of Källgren and Depui *et al.* in order to create a packaging system comprising a proton pump inhibitor in combination with a non-steroidal anti-inflammatory drug. As stated in Depui *et al.*, the motivation to create the disclosed combination dosage form originates from a desire to give a patient a composition that is convenient to take, leading to greater compliance. It is the position of the examiner that similarly, a combination dosage regimen given in one package will also lead to greater patient compliance, which a use for drug packaging systems that is recognized in the art. As the disclosed invention of Källgren

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is not limited to any particular types of drugs to be packaged, one of ordinary skill can expect to create a drug pack comprising dosages of omeprazole and diclofenac in accordance with a combination dosage regimen with a reasonable expectation of success.

### ***Response to Arguments***

Applicant's arguments filed 11 August 2003 have been fully considered but they are not persuasive.

The applicant's arguments are based upon a narrow interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111.

In the passage in the M.P.E.P. that the applicant has cited, the word "unsatisfactory" is used in the sense that a proposed modification would result in an inoperable species. In the view of the examiner, it is clear from the prior art that in the disclosure in Depui *et al.*, the phrase "not convenient or satisfactory" is used to denote that such a treatment is operable, yet merely not preferred, instead of a completely inoperable species, as the applicant suggests. However, even non-preferred embodiments constitute prior art, as prior art is relevant for all that it contains. Here, the Depui *et al.* patent merely recites what is already known in the art. Furthermore, this disclosure in Depui *et al.* does not explicitly state whether or not the lack of effectiveness in separately administering a non-steroidal anti-inflammatory drug and a proton pump inhibitor also considers the benefits provided by an effective packaging system. Therefore, this disclosure does not explicitly teach away from the examiner's interpretation and combination of the prior

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art. Therefore, the packaging system arising from the applicant's interpretation of the collective prior art is not, in the view of the examiner, the only possible result from the combination of the prior art.

Regarding the applicant's arguments concerning Claims 1-3, the applicant is reminded that what is being claimed is a packaging system, not a drug combination. The effectiveness of the packaging system is neither limited nor enhanced in any way by the selection of specific types of solid unitary dosage forms to be included in the instantly claimed packaging system, nor is it limited or enhanced in any way by the selection of the types of active ingredients contained within the solid unitary dosage forms to be included in the instantly claimed packaging system. In any case, all claims remain obvious in view of the prior art.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj0

  
THURMAN K. PAGE  
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